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Kidney Access Device

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ABSTRACT

Introduction: Percutaneous nephrolithotomy is the most complicated stone surgery technique to learn. The steep learning curve is related mainly to obtaining precise renal access by puncturing the targeted calyx. A minimally misaligned puncture may lead to torrential bleeding, failure of the surgery, and complications. Renal puncture can take a long time, and the increased fluoroscopic time is a hazard for the patient and surgeon.

Methods: To aid in renal puncture and overcome the learning curve associated with learning the renal puncture technique, we designed a kidney access device (KAD), which helps align the 3-dimensional targeted calyx under fluoroscopy for precise needle placement. The KAD allows access to calyces at all angles. A 3-step puncture technique was formulated for puncturing the kidney using the KAD in a porcine model (with comparable renal size and anatomy with humans). To evaluate the practicality of the KAD and its possible advantages and limitations, the KAD was used to puncture 3 targeted calyces of bilateral kidneys in 4 pigs. Guidewires were inserted into the renal collecting system through the placed needle.

Results: Mean time per puncture was 4 ± 2 minutes (n = 24). Necropsy showed no retroperitoneal hematoma, visceral organ injury, or active bleeding from kidneys in any of the pigs. Kidneys were dissected and precise intrarenal placements of guidewires in relation to targeted calyces were noted at all 24 sites.

Conclusions: The KAD with the 3-step technique aids in the safe and accurate renal puncture, even in novice hands, while drastically reducing operative and fluoroscopy time. The KAD may also be used to access other organs and has potential applications in minimally invasive surgery.

Key Words: PCNL, Percutaneous nephrolithotomy, Kidney puncture, Kidney puncture device, Renal puncture.

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INTRODUCTION

Percutaneous nephrolithotomy (PCNL) is the favored endourologic procedure for large (>20 mm) renal calculi, offering patients a low-morbidity procedure with high efficacy in terms of stone clearance. PCNL has proved its efficacy and has stood the test of time compared with open surgical techniques[1] and extracorporeal shock-wave lithotripsy. Over time, developments in radiologic imaging, urologic instruments, and techniques have advanced the frontiers for the success and safety of PCNL. The procedure is now recognized to have a low failure rate and to be a superior alternative to shock-wave lithotripsy for treating large renal calculi.

The initial step of PCNL entails obtaining percutaneous access to the kidney. The kidney puncture is critical, and it is difficult to obtain an appropriate renal tract.[2] Although fluoroscopy and ultrasound guidance provide well-established methods of percutaneous renal access,[2,3] these interventions are technically demanding and risky, especially in unfavorable settings such as complex anatomy.[4] Both ultrasound- and fluoroscopy-guided puncture techniques provide only a 2-dimensional view of the anatomy, and reaching the exact site of puncture can be more difficult. There have been reports of the use of computed tomography[5] and magnetic resonance imaging,[6] but these tools are time consuming, are not ergonomic, and do not take the movements of the kidney into account.

Overall, C-arm fluoroscopy remains the most commonly used method[7] to obtain initial renal puncture for PCNL, but it involves patient and operator irradiation. It has been shown that when a fornix is targeted,[8] there is decreased risk for injury to the large vessels in the kidney. Repeated attempts at gaining the accurate puncture increases the risk for renal injury and bleeding, which can lead to abandoning the surgery or rarely requiring intervention.

In the past, several technical modifications were attempted to simplify the procedure for initial kidney puncture, such as laser guidance,[9] robot assistance,[10] and retrograde endoscopy-guided approaches.[11] However, until now, none of these ideas has become routine, mainly because of poor cost-effectiveness.

Thus, it has been felt that there is a need for a device that would (1) help in increasing the accuracy and safety of renal puncture, (2) decease the time needed for renal procedure, (3) reduce the radiation dose to the patient and surgeon, (4) avoid the direct exposure of surgeons' hands to radiation when handling the puncture needle under fluoroscopy, and (5) make it easier to transfer the puncture technique to the next generation.

Given these needs, there have been a few recent studies reported in the literature that have attempted special techniques or used devices to help in renal puncture.[12–16] The biggest drawback of the described devices is the lack of in vivo testing. It is well understood that in vivo, muscle and fascial deformation as well as kidney movement may diminish calyceal puncture success.

We aimed to design a mechanical device that would aid in renal puncture and thus improve the safety and efficacy of PCNL. Such a device would fulfill the aforementioned objectives. Also, to overcome the drawbacks of other reported instruments, we planned to do the trial in vivo using a live porcine model so as to closely replicate the operative process in humans and thus undertake a better evaluation of its clinical reliability.

MATERIALS AND METHODS

Description of the Instrument: The Kidney Access Device

The purpose of the kidney access device (KAD) is to stabilize the needle and align it for PCNL needle puncture, thus allowing precise needle placement. The base of the KAD is an electromagnet, which when it is switched on attaches firmly to a landing platform that is attached to the operating table. The platform can be fixed to any presently used operating table along the side rails. Our device has 2 hydraulic arms with a translucent tube attached distally, which can rotate and allow a large degree of manipulation to allow access to upper, middle, and lower pole calyces. The hydraulic arms are fixed to the operating table with the help of an anchoring magnetic base. The

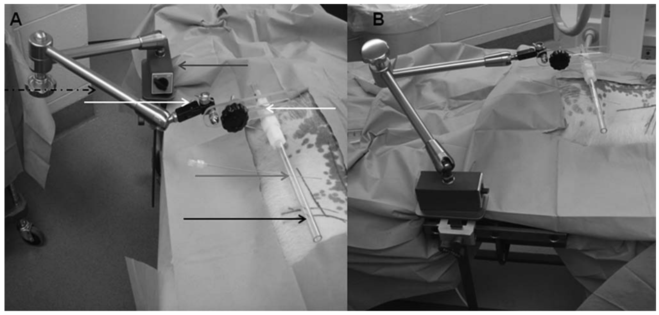

Figure 1. Parts of the KAD. (A) Top marker: Base magnet, which can be switched on to anchor the KAD to the platform attached to the operating table. (B) Black interrupted marker: (2nd marker from the top). Golden-colored hydraulic arms of the KAD for gross alignment of the puncture needle. These arms allow targeting of upper, middle, and lower pole calyces and can be fixed in positon by tightening of the central golden screw. (C) Third marker from top marker: Screw for finer horizontal movements of the puncture needle. This allows finer movements of the needle holding tube and the needle to compensate for the kidney movements with respiration. (D) 4th marker from top: The horizontal slider allows the medial and lateral movements of the needle, required for step 3 of the renal puncture. The horizontal movement of the needle can be made by moving this slide. (E) 5th marker from top: Shows the small hole in the distal radiolucent tube, through which the puncture needle passes. The hole is made such that it is snug, such that it holds the needle in place and allows it to be pushed through when in position. (F) Bottom marker: Shows the radiolucent distal tube, which holds the puncture tube.

puncture needle passes through a radiolucent tube that is secured to the hydraulic arm, allowing accurate alignment **(Figure 1)**. The needle-holding tube can move in the horizontal direction and rotate in any axis, and being radiolucent, only the needle is visible under fluoroscopy. Fine needle compensation for renal movement because of breathing can be done by a special adjusting screw. For full description of the device's parts, see **Figure 1**. By using fluoroscopy to ensure precise placement of the needle, the KAD allows access to calyces from all angles relatively easily.

Animal Model for KAD Trial

The protocol for the research was approved by the institutional review board as well as the institutional animal care and use committee. We chose to test our device in a 65-lb porcine model. This was based on the fact that pigs have comparable renal size and anatomy with that of humans. A total of 4 pigs were used. Using the KAD, we

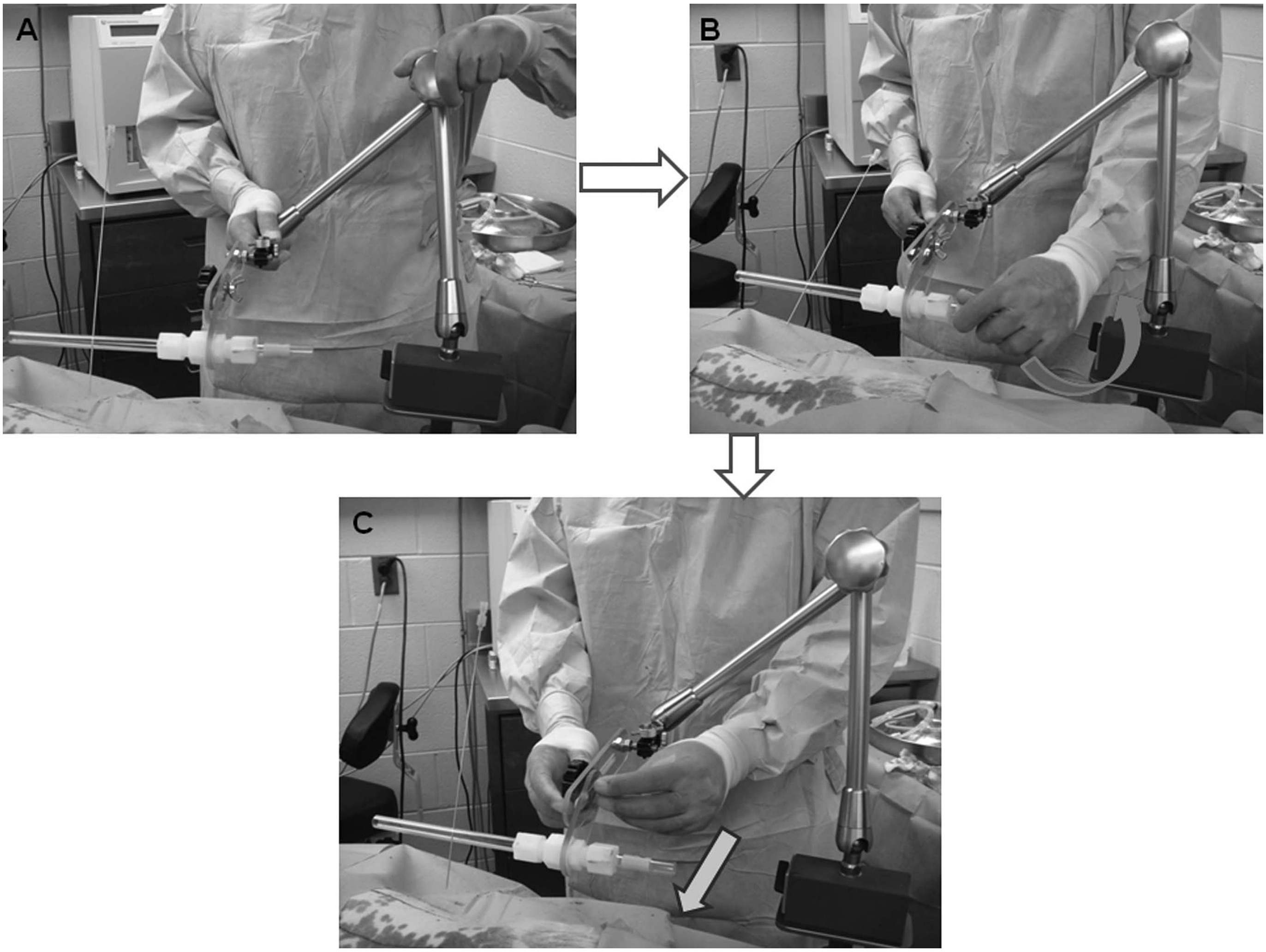

Figure 2. (A) Step 1 of using the KAD for renal access. The KAD is mounted on the operating table–attached platform using the base magnet. Using the golden hydraulic KAD arms, the distal translucent tube is aligned in renal direction. (B) Step 2: The puncture needle is aligned in the vertical axis of the targeted calyx, under fluoroscopy, such that it is parallel to the calyx. (C) Step 3: Using the distal slider, the puncture needle is moved forward, such that the needle superimposes the targeted calyx, and confirmed under fluoroscopy. The needle can then be pushed in to puncture the kidney until a sensation of "giveaway" is felt and confirmed by the return of urine.

targeted 3 calyces of each kidney in the 4 pigs for a total of 24 punctures.

Trial Protocol

The pig was intubated, and under general anesthesia, the pig was positioned in a supine position. A 2-inch lower abdominal midline incision was made, and the peritoneum was entered. The urinary bladder was identified in the pelvis, and the bilateral ureters were identified and dissected free close to the urinary bladder. Ureteric catheters were then inserted into the ureters to reach the respective renal pelvis and were secured in place. The distal ureters were ligated. The ureteric catheters were brought out from the lower part of the abdominal incision. The abdominal incision was then closed.

The animal was then positioned in a prone position on the operating table and secured on the operating room table. The KAD was then placed on the landing platform attached to side of the operating table and anchored in place by switching on the base magnet **(Figure 2A)**. Radiopaque dye was instilled into the renal pelvis through the previously placed ureteric catheters to opacify the renal pelvicalyceal system. For the first puncture, the upper pole posterior calyx was chosen; this was subsequently followed by the midposterior calyx, and the lower pole posterior calyx was targeted last.

Kidney access was planned using a 3-step puncture technique (Figure 2). The first step was to align the needle in the horizontal direction of the targeted calyx under fluoroscopic guidance; this was done after positioning the image intensifier (fluoroscopy) vertically, such that it was at a right angle to the animal and the puncture needle. The second step was to rotate the needle-holding tube (of the KAD) in the same vertical axis as the targeted calyx. This was done after rotating the fluoroscope to approximately 30° such that the targeted calyx appeared as a black dot on fluoroscopy as the image intensifier was in the line of the targeted calyx, and the puncture needle looked the same, which confirmed that both the targeted calyx and the needle were in a parallel vertical plane **(Figure 2B)**. In the final step, the needle was superimposed over the targeted calyx by moving the KAD holding tube forward. Appearance of a single dot on fluoroscopy confirmed that the needle was overlying the targeted calyx **(Figure 2C)**. The 3-step technique was similar to the "bull's-eye technique" described in the literature. The respiration of the kidney was withheld at this time for approximately 30 seconds so that renal movements with respiration were avoided. For the final step, the puncture needle was pushed through the skin and subcutaneous structures until a feeling of giveaway was felt. A successful puncture was confirmed under fluoroscopy and also by the return of clear urine through the puncture needle **(Figures 3A and 3B)**. A guidewire was then inserted through the needle and manipulated down the ureter and confirmed in place with fluoroscopy **(Figures 3C and 3D)**. After the guidewire was secured in place, the subsequent midpole and lower pole calyceal punctures were done following the same puncture steps. This was followed by similar renal punctures done on the contralateral kidney with insertion of guidewires that were secured in place. Timing for each puncture was recorded.

During the whole procedure, the animal was carefully monitored for hemodynamic stability and stable ventilator settings. The pig was then kept under anesthesia for 1 hours while being monitored for any change in hemodynamic or ventilator settings.

Vertical incisions were made on bilateral flanks along the lateral borders of the psoas muscles. The retroperitoneum were exposed and the kidneys were dissected free. Any injury to surrounding organs, such as the pleura, liver, or bowel, was evaluated, along with any retroperitoneal hematoma or active bleeding from the kidney. The positions of the guidewires were also noted. The renal pedicles were then ligated and the animal was euthanized. The kidneys were then dissected, and the positions of the guidewires in relation to the targeted calyces were noted.

RESULTS

Mean time per puncture was 4 ± 2 min ($n = 24$). Intraoperatively, all calyces in the upper, middle, and lower poles of the kidney could be easily accessed with the KAD. The device also allowed fine adjustments of the puncture needle.

Postprocedural dissection of the kidneys and surrounding organs revealed no retroperitoneal hematoma, visceral organ injury, or active bleeding from kidneys in any of the pigs. After the dissection of kidneys, analysis of the position of guidewires in relation to the targeted calyxes was done. The precise intrarenal placements of guidewires in relation to targeted calyces were noted at all 24 sites.

DISCUSSION

PCNL is a specialized, minimally invasive urologic procedure that remains the surgical procedure of choice for treating large renal calculi and calculi resistant to extracorporeal shock-wave lithotripsy treatment. Despite its popularity, it is an invasive procedure that can result in significant morbidity and even mortality. PCNL has a steep learning curve and is a difficult procedure to master, taking about 60 PCNL procedures for surgical competence and 115 procedures for excellence.[18]

With technological advances, there have been endeavors to invent a device that would make this procedure safe while decreasing the learning curve associated with it. Even though many innovative devices have been reported,[12–17] each has its drawbacks, and most have not been evaluated in an animal trial. The main concern when performing PCNL is the location of the stone and an accurate initial renal puncture to target it. Also if the renal puncture is not done at "end on calyx," it can result in torrential bleeding from the vessels which run on the sides of the calyces. An inaccurate renal puncture could also result in injury to visceral organs, substantial bleeding, or loss of kidney.

Among the many techniques and instruments that have been reported to perform safe PCNL, each has its respective shortcomings. One such method is an optical puncture system. In this method, a micro–optical light lead is inserted through the puncture needle and then connected

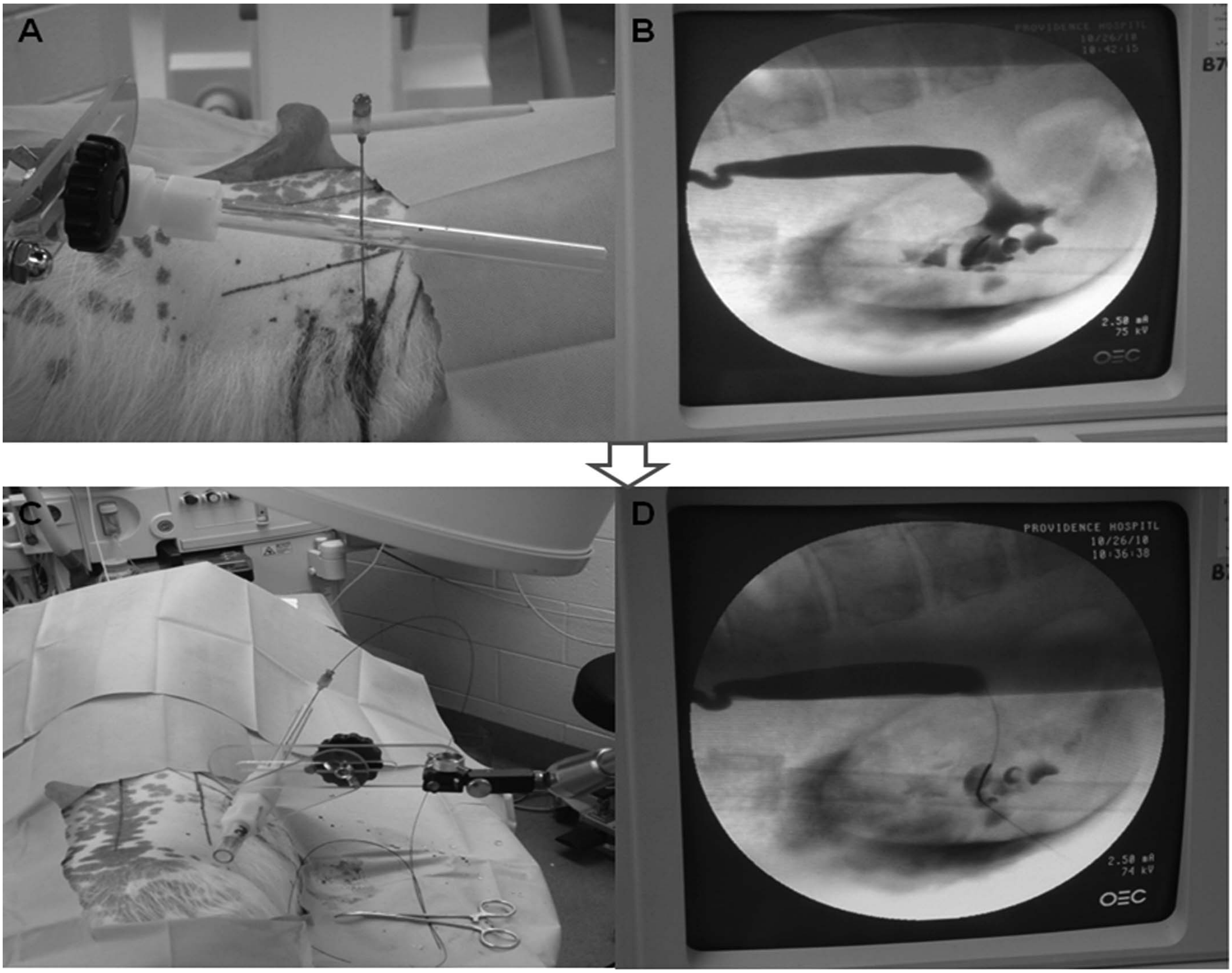

Figure 3. (A) Renal puncture with the help of the KAD. (B) Accurate placement of needle in the renal calyx, confirmed on fluoroscopy. (C) Guidewire placed into the renal collecting system through the KAD-aided renal puncture. (D) Guidewire placement in the renal pelvicalyceal and down the ureter through the renal puncture needle confirmed under fluoroscopy.

to an endoscopic camera system,[18] so that the calyces can be identified and the stone can then be located. However, this technique has several limitations, chiefly that the scopes used for the procedure cost thousands of dollars, making the device not a cost-effective alternative. Another limitation of using the endoscopic camera system is the steep learning curve. PCNL renal puncture in itself is a difficult procedure to master, and along with the endoscopic camera system, the amount of expertise required increases dramatically.

A method that uses computer software along with a gantry also exists.[13] In this method, images of the renal calyceal system are taken and then sent to a laptop computer containing the software.[13] With these images, the surgeon can mark the area to puncture by clicking the computer mouse on a specific image. Once the surgeon clicks on the image, the software determines the needle trajectory and provides the settings for 3 axes on the gantry. After this is done, the needle can be placed on the needle holder, and by using the calculations the software provided, the targeted calyx can be punctured.[13] This software-based method involves a lot of equipment and requires knowledge on how to use the software, and these limitations make it difficult to use on a routine basis.

These elaborate methods are reserved for those with extensive training and resources and not meant for routine use in hospitals, and with rising health care costs, they are not practical to be used on a regular basis.

Some of the advantages of the KAD over other reported such renal puncture aids are as follows:

1. The KAD is cost effective, costing <$700 to make. Other reported devices require complicated and advanced software and other parts, resulting in higher costs.

2. It is accurate. We made the KAD using 2 hydraulic arms, a radiolucent needle holder, and some clamps; our device provides a precise means by which to enter the renal calyces. In each of our punctures, the specified renal calyxes were easily targeted, and no postprocedural complications were noted.

3. The KAD does not require any extensive training or expertise in computer software.

4. It can easily be used by a novice and accurately applied with a 3-step technique as we describe.

5. In addition to increasing the safety of renal puncture, the KAD avoids the direct exposure of radiation to the surgeon's hands while performing the procedure.

6. Also, the KAD reduces the radiation exposure to the patient, as the amount of fluoroscopy used is much less, because the time required for the renal puncture is reduced.

Although our device has many advantages, we do feel that it needs to be critically evaluated in a human trial, as minor problems could be encountered when using the KAD in humans. Some of the possible anticipated problems of using the KAD in humans are as follows:

1. Minor adjustments with the finer movements of the needle-holding tube may be required to compensate for the differences in renal anatomy between humans and pigs.

2. Depending on the body wall thickness (which can be variable in humans depending on body mass index) the lengths of the hydraulic arms of the KAD may need to be increased when using the device on obese patients.

3. Human anatomy can be variable, and more careful planning would be needed when accessing kidneys with congenital or developmental variations.

4. We did not measure the actual radiation used during this initial trial of the KAD. An accurate measurement of the radiation used in the procedure is required.

CONCLUSIONS

The KAD, along with the 3-step technique, aids in the safe and accurate placement of the puncture needle, even in the hands of a novice. The device also allows less operative time and subsequently less exposure to fluoroscopy for both the surgeon and the patient. The hydraulic arms and rotating axis of the radiolucent tube allow precise placement of the puncture needle. In our trial, all punctures accessed the calyces accurately and easily and with minimal bleeding. This is the first report of a kidney puncture device with a successful animal trial. This device can also be used in many other surgical procedures and allows a minimally invasive approach.

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